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(71) Applicant : **CARDIAC PACEMAKERS, INC.**
Hamline Avenue North 4100
St. Paul, Minnesota 55112-5798 (US)

(72) Inventor : **Dreher, Robert**
3055 Woodbridge Street
Roseville, Minnesota 55113 (US)
Inventor : **Kuhnley, Brian**
15388 76th Avenue North
Maple Grove, Minnesota 55369 (US)
Inventor : **Sowder, Conrad L.**
5236 12th Avenue North
Minneapolis, Minnesota 55417 (US)

(74) Representative : **Zinnecker, Armin, Dipl.-Ing. et
al**
Lorenz-Seidler-Gossel, Widenmayerstrasse
23
D-80538 München (DE)

(54) **Fibrillation induction method for implantable devices.**

(57) A method and apparatus for generating a multiphasic defibrillation/cardioversion waveform as well as a multiphasic fibrillation inducing pulse train. The multiphasic fibrillation inducing waveform being applied to the same electrodes as the defibrillation/cardioversion waveform.

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BACKGROUND OF THE INVENTION

The present invention relates to implanted arrhythmia control devices, and more particularly to a non-invasive method and apparatus for inducing arrhythmias after the device is implanted. More specifically, it relates to a non-invasive method and apparatus for generating fibrillation inducing pulse trains for the purpose of testing an implanted cardioversion/defibrillator.

Ventricular fibrillation typically must be induced when an automatic implantable cardioverter defibrillator is implanted and for follow-up studies to test the effectiveness of the automatic implantable cardioverter defibrillator in defibrillating.

When implantable arrhythmia control devices are used, it is desirable to allow stimulation of the heart to induce arrhythmias after the device is implanted, without the need to introduce a separate stimulating lead/wire. That is, a non-invasive method of inducing arrhythmias is desirable.

In order to induce fibrillation for the purpose of testing an implanted arrhythmia control device, burst or ramped burst pacing at very fast stimulation rates has been used to induce ventricular fibrillation in some patients. However, due to the small energy levels involved and the relatively small size and placement of the pacing electrode system, this method does not successfully induce ventricular fibrillation. Programmed electrical stimulation or non-invasive premature stimulation has also been used to induce ventricular tachycardia, but does not always reliably induce ventricular fibrillation. Programmed electrical stimulation or non-invasive premature stimulation commonly consist of delivering a series of fixed rate pace pulses, followed by 1 to 5 pacing "extra-stimuli" at various shorter intervals coupled to the last fixed rate pulse. Both programmed electrical stimulation/non-invasive premature stimulation and burst pacing use the much smaller pacing electrodes which tend to localize the stimulation. Fibrillation is more easily induced when large portions of the heart are stimulated simultaneously.

While these prior systems generally are effective, there is room for improvement.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a method and apparatus for generating a multiphasic fibrillation inducing pulse train via the defibrillation/ cardioversion leads and electrodes of an already implanted defibrillator to thereby test the implanted defibrillator non invasively.

Briefly, the present invention is directed to a method and apparatus for use with an implanted defibrillator, having an external programmer including telemetry means. The telemetry means is used to

communicate with an implantable device incorporating a multiphasic circuitry for non-invasively delivering a fibrillation inducing pulse train via the defibrillation/cardioversion leads and electrodes of the already implanted defibrillator. In this manner, the present invention facilitates testing of an already implanted defibrillator without the need to induce fibrillation by invasive techniques.

The above and other objects and advantages will become more readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic diagram of the circuitry of an implanted defibrillator, capable of generating a multiphasic defibrillation waveform, and adapted to be used with an external programmer, including telemetry means, in accordance with the present invention to deliver a fibrillation inducing pulse train via the defibrillation/cardioversion leads and electrodes of the implanted defibrillator.

Figure 2 is a flow chart illustrating the operation of the circuitry shown in Figure 1.

Figure 3 is a graphical representation of a multiphasic fibrillation inducing pulse train generated by firmware in the circuitry of FIG. 1, which is used to induce fibrillation in a heart for the purpose of testing an implanted cardiac defibrillator.

Figure 4 is a graphical representation of an approximation of the fibrillation inducing pulse train shown in Figure 3, which can be generated by utilizing the ratiometric capabilities of the circuitry of Figure 1.

DETAILED DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates an implantable electrical circuitry for generating a multiphasic defibrillation waveform. An external programmer, including telemetry means, is used to communicate with the implanted circuitry to deliver fibrillation inducing pulse trains via the defibrillation/cardioversion leads and electrodes of the already implanted defibrillator in accordance with the present invention.

Techniques for defibrillation/cardioversion have evolved over the years from a truncated exponentially decaying waveform of a capacitor to more sophisticated waveforms, such as multiphasic waveforms. In this regard, it has been found that multiphasic waveforms often are more effective in defibrillating the heart. The circuit for generating multiphasic defibrillation waveforms shown in FIG. 1, and the operation of which is illustrated by the flow chart in FIG. 2 is more fully disclosed in copending U.S. Patent Application S.N. , entitled: Method

and Apparatus for Generating Multiphasic Defibrillation Waveforms Based on Pulse Width Ratios, which

was filed on the same date as this application. The disclosure of which copending application is hereby incorporated by reference.

In accordance with the present invention, the circuit shown in FIG. 1 for example, can be used to remotely induce fibrillation for the purpose of testing the effectiveness of the implanted defibrillator prior to discharging the patient from the hospital.

Traditionally, testing of an implanted defibrillator has been accomplished by passing a catheter into the patient and inducing fibrillation via the catheter. Recently, however, remote control of an already implanted defibrillator has been accomplished by using an external programmer device or other similar device. An external programmer includes telemetry means that provides non-invasive control and interrogation of an implanted defibrillator. The external programmer may include a telemetry wand to communicate with the implanted device via RF signals.

According to the present invention, by using an external programmer or other similar device, fibrillation can be induced via the leads and electrodes of the already implanted defibrillator.

With reference to FIG. 1, an external programmer 150 (or other similar device) having a telemetry wand 152 is used to non-invasively cause the circuitry 100 of the present invention to deliver a multiphasic fibrillation inducing pulse train, rather than a multiphasic defibrillation waveform. An ideally effective fibrillation inducing pulse train 140 is illustrated in Figure 3. All of the pulses constituting the pulse train 140 have the same nominal voltage V_n , which is typically on the order of 15 volts but may be as low as 9 volts, with successive pulses alternating in polarity between negative and positive polarity. The pulse width t_w for each pulse is preferably 1.1 milliseconds, while the delay time t_d between successive pulses can range from 30 to 50 milliseconds. A delay time of 30 milliseconds provides a high rate of pulses, while a 50 millisecond delay time provides a slower rate of pulses. The pulse widths are shorter than those which are used for defibrillation purposes. Likewise, the pulse width percentages P_2, P_3, \dots, P_n are all programmed to equal 100 percent such that all pulses subsequent to the first have the same pulse widths t_2, t_3, \dots, t_n as the first pulse.

The circuitry 100 is provided with logic which, upon detecting via the external programmer 150 or other similar device the command to induce fibrillation, directly causes a pulse train to be emitted with a predetermined pulse width equal to t_w , a nominal voltage equal to V_n , and delay time equal to t_d . The logic can accomplish this by causing the charge control logic 108 to charge the capacitor 128 to a predetermined voltage equal to or slightly higher than V_n . Next, the additional logic temporarily overrides the circuitry 100 of Figure 1 causing switches $s1$ and $s4$ to close for t_w milliseconds, then causing the switches to open for

the delay time t_d and thereafter closing switches $s2$ and $s3$ for t_w milliseconds, this process being repeated by the additional logic until a predetermined period of time equal to the desired duration of the pulse train (preferably 2 - 5 seconds) has elapsed. In this manner, the pulse train is provided without having to detect any voltages other than the starting voltage of the capacitor.

Alternatively, Figure 4 illustrates a close approximation 140' of the pulse train 140 of Figure 3, which can be generated by using ratiometric capabilities of the circuitry 100. This approximation 140' is primarily achieved by choosing values of V_0 and V_1 which, in addition to being slightly greater than V_n , are very close to one another such that a shorter pulse width t_1 (comparable to t_w , and shorter than that which is used for defibrillation purposes) is achieved for the first pulse. Likewise, the pulse width percentages P_2, P_3, \dots, P_n are all programmed to equal 100 percent such that all pulses subsequent to the first have the same pulse widths t_2, t_3, \dots, t_n as the first pulse.

The approximated fibrillation inducing pulse train 140' can also be generated without the need for programming the pulse width percentages. Instead, the circuitry 100 can be provided with logic which upon sensing via the external programmer 150 or other similar device the need to induce fibrillation, causes the contents of the data buffer 112 to be provided to the pulse control logic 118 in place of the result from the multiplier 110. Consequently, rather than providing the result from the multiplier 110 to the pulse control logic 118, the actual value of t_1 from the data buffer 118 is provided. Hence, all subsequent pulses are automatically delivered with the same pulse width as t_1 .

Furthermore, modifications may be made to the circuitry 100 shown in Figure 3, for the purpose of delivering fibrillation inducing pulse trains, without departing from the scope and spirit of the present invention. For instance, the pulses or "mini-shocks" can be delivered in alternating polarity as set forth above, or all in the same polarity. Each pulse is delivered as a monophasic fixed pulse width shock, with short charge cycles between pulses. The shocks are delivered to the defibrillation electrodes by the four switch S_1, S_2, S_3, S_4 switch bridge network. Such use of the same output circuit for the fibrillation inducing pulses as the normal defibrillation pulse delivery has not previously been provided. The very high rate delivery through the larger shocking electrodes allow stimulation of a larger part of the heart.

Further, retriggering capability is provided to allow the delivery of a burst of pulses for any desired duration. The delivery being controlled by a user pressing and holding a button or key on the programmer. In a preferred embodiment the pulse train is 2 - 5 seconds long.

Alternative embodiments of the invention would provide higher rates of delivery of the fibrillation pulses, for instance at 8 to 16 milliseconds. Lower pulse amplitudes would result in less energy delivery, and higher output impedance with provide for better current limiting. 5

The above description is intended by way of example only and is not intended to limit the present invention in any way except as set forth in the following claims. 10

Claims

1. An implantable apparatus for generating a defibrillation/cardioversion waveform for application to defibrillation electrodes, including an external programming means for causing said implantable apparatus to generate a multiphasic fibrillation inducing pulse train, each of said pulses being separated by a delay time t_d with each pulse having a pulse width t_w and a nominal voltage V_n . 15 20
2. The apparatus of claim 1, wherein said delay time t_d is set between 30 - 50 milliseconds, said pulse width t_w is 1.1 milliseconds, and said nominal voltage V_n is 15 volts for each of the pulses, said pulse train being 2 - 5 seconds long. 25
3. The apparatus of claim 1, wherein said fibrillation inducing pulse train is delivered to said defibrillation electrodes. 30
4. The apparatus of claim 1, wherein said implantable apparatus includes logic means which in response to said external programming means causes said implantable apparatus to generate a fibrillation inducing pulse train with a predetermined pulse width and a predetermined time delay. 35 40

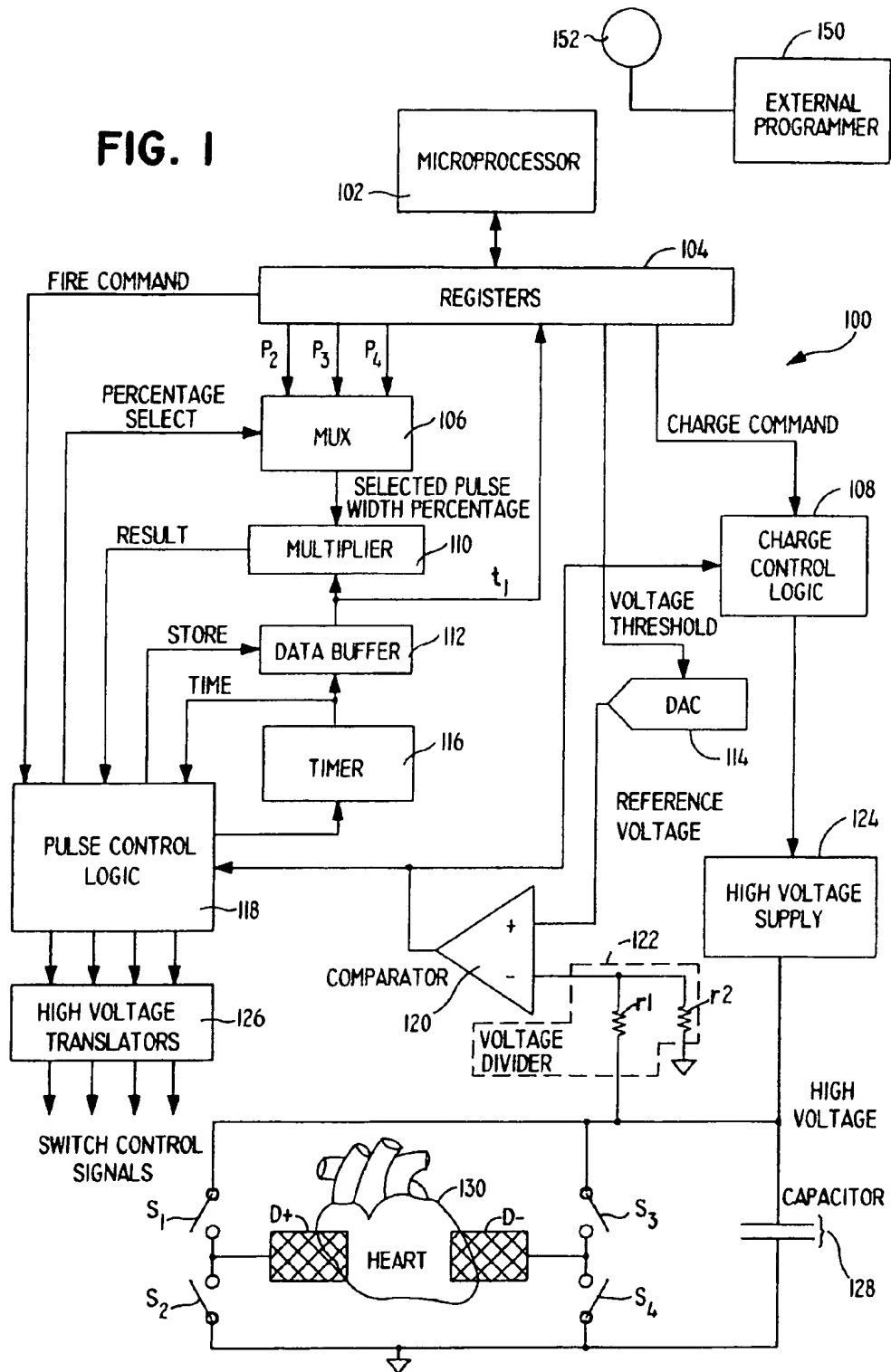
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FIG. 1



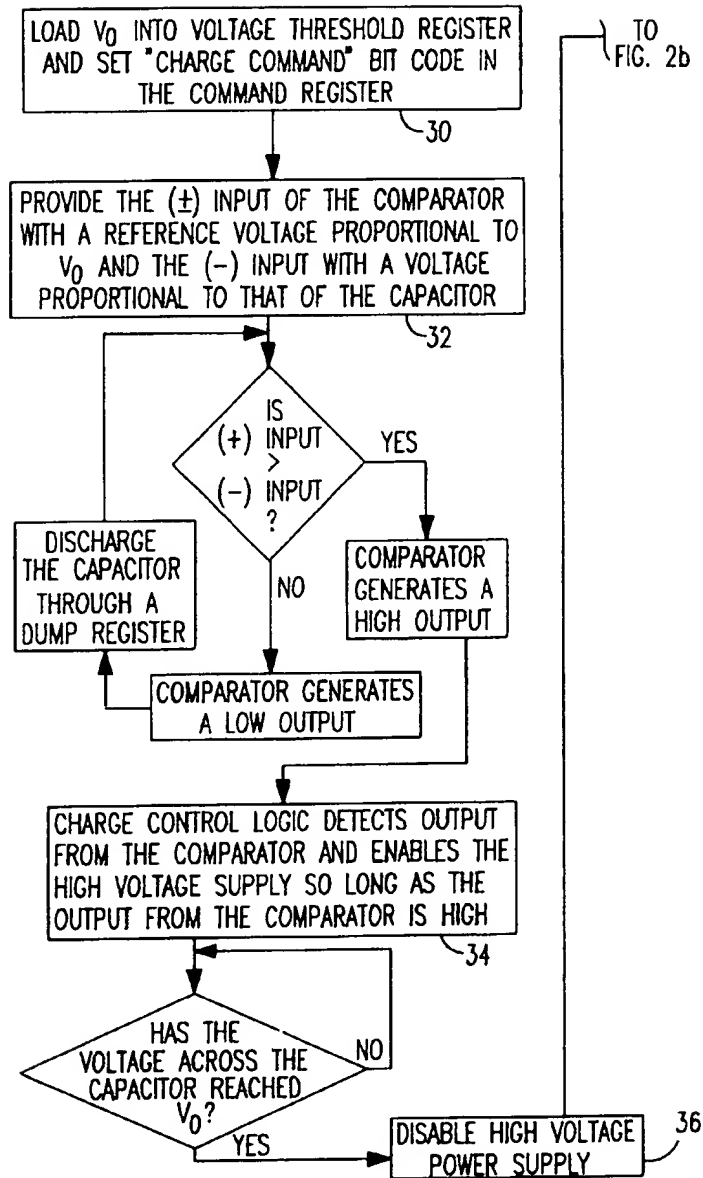


FIG. 2a

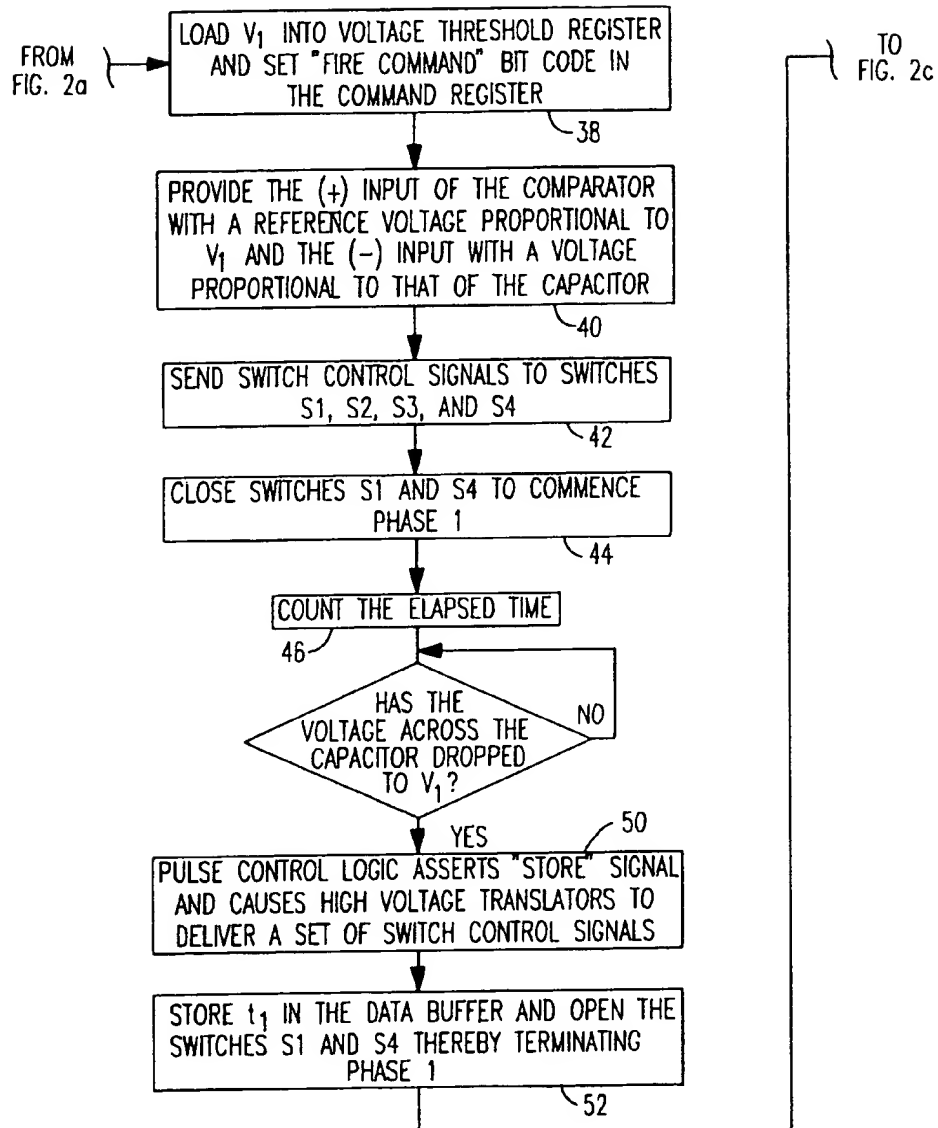


FIG. 2b

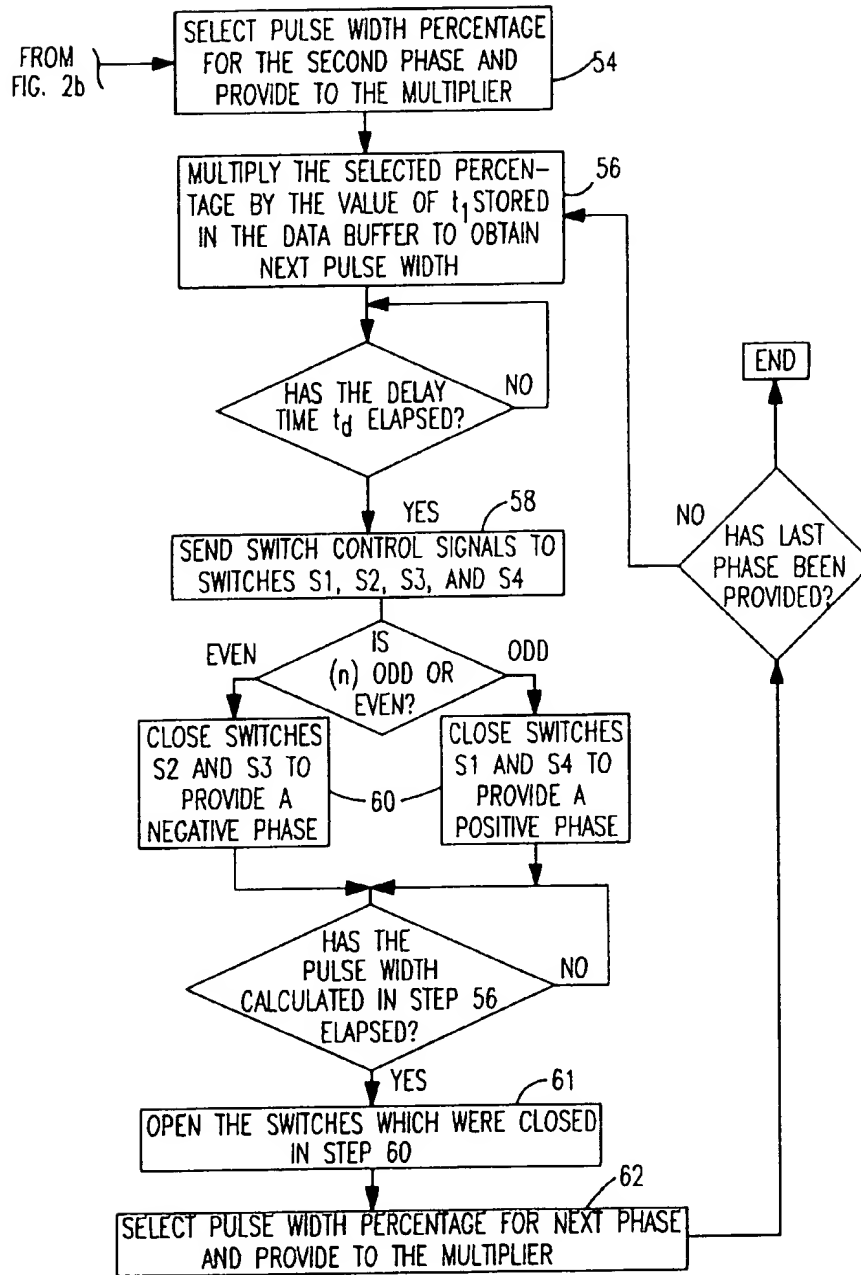


FIG. 2c

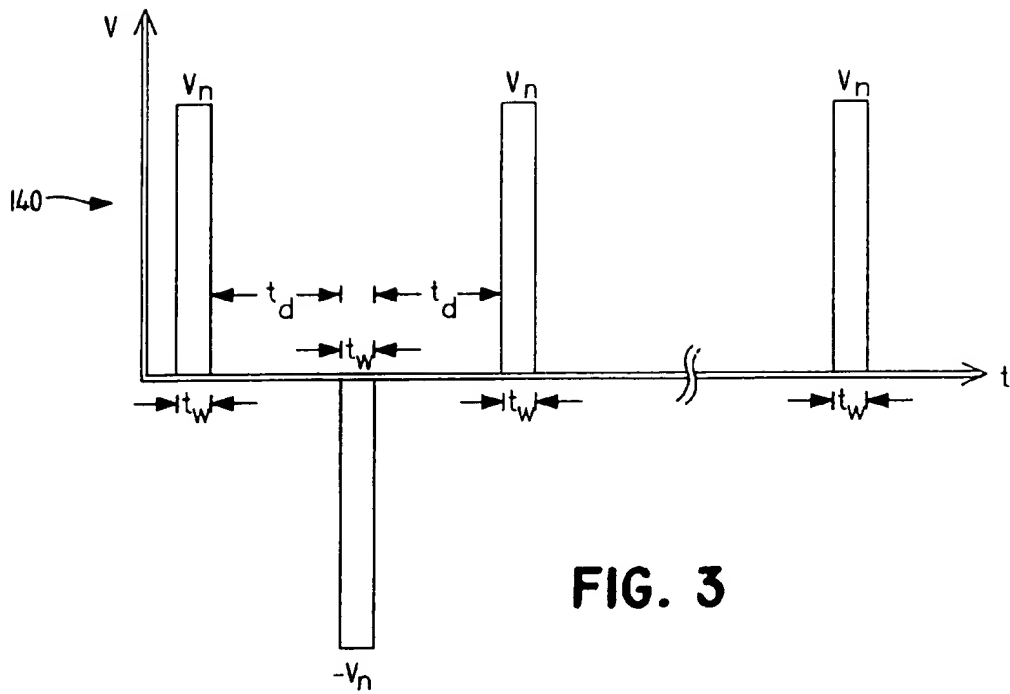


FIG. 3

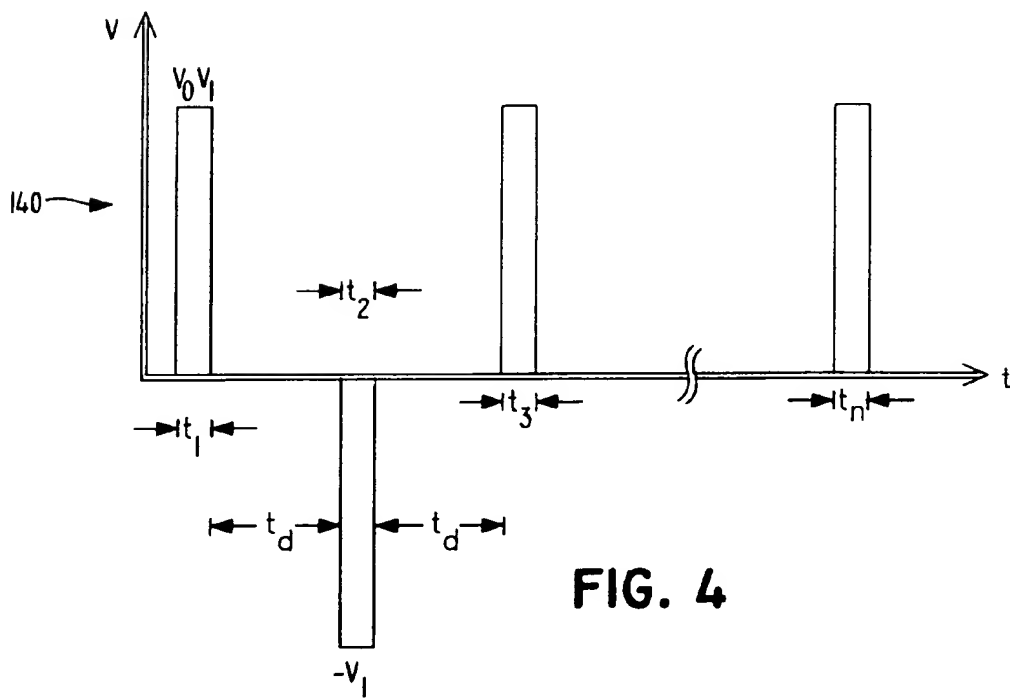


FIG. 4